REMARKS

Claim 2 has been cancelled. Claim 1 has been amended. Claims 1 and 3 are now pending in this application. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Priority

The Examiner states that the priority date of the instant application is only entitled to the international filing date of July 22, 2003 (the date of the PCT application) because an English translation of Applicants' foreign priority document has not been submitted.

An English translation of a priority document is not necessary to claim priority, but only to overcome an intervening reference (see M.P.E.P. 201.15). As no intervening reference has been cited, it is not necessary for Applicants to provide an English translation of a priority document.

Applicants assert that the priority claim has been properly made by listing of the priority document on the Declaration/Power of Attorney document which was filed with the application and by submission of a certified copy of the foreign application (see M.P.E.P. 201.14(b)). As this application is the US National phase under 35 U.S.C. § 371, a copy of the certified priority document is conveyed by the International Bureau (PCT Rule 17.2(a)). Page 1 of the Office Action Summary states that the certified copy of the priority document has been received.

In view of Applicants' comments above, acknowledgement of Applicants' priority claim is respectfully requested.

Rejection under 35 U.S.C. § 102(b)

Claims 1-3 are rejected under 35 U.S.C. § 102 (b) as anticipated by Kimura, et al. (JP Publication No. 10-182458).

The Office Action states that Kimura, et al. teach indomethacin-containing compositions having the same components as claimed by Applicants. Although Kimura, et al. do not teach the

same percentages by weight of components, the Examiner asserts that such differences do not support patentability unless there is evidence of criticality.

Kimura, et al. describe a gel formulation, not the gel/cream formulation taught by Applicants. Furthermore, Kimura, et al. do not teach the oil content of 7-30% and do not teach that the sorbitan monostearate component has a melting point of at least 40°C as claimed by Applicants.

Regarding the melting temperature, Applicants respectfully point out that the SIGMA Aldrich catalog provided with the Office Action gives the melting point of PEG, not polyethylene glycol monostearate as taught by Kimura, et al. Furthermore, the melting point of PEG and PEG derivatives will differ with the size of the PEG polymer. For example the melting point of PEG 400 monostearate is 35-40 °C while the melting point of PEG-600 monostearate is 41 °C (see attached technical bulletins; Attachment A, 3 pages). The present claims are specifically directed to where the "glyceryl monostearate, sorbitan monostearate, stearyl alcohol, and polyethylene glycol monostearate has a melting point of 40°C or higher" (claim 1 as amended).

Regarding criticality of the claimed components, Applicants provide the attached 132 Declaration and the following comments. Inclusion of "glyceryl monostearate, sorbitan monostearate, stearyl alcohol, and polyethylene glycol monostearate [having] a melting point of 40°C or higher" as presently claimed (claim 1) is critical for avoiding phase separation that occurs at higher oil concentrations.

The relatively high oil content of Applicants' claimed invention provides Applicants' gel/cream composition with desirable characteristics such as a pleasant non-sticky feel upon application. The compositions of Kimura, et al. do not have this desirable characteristic because Kimura, et al use a lower oil content (3%). However, with an oil content of 7-30%, phase separation is a problem. This is not a problem for Kimura, et al. because Kimura, et al. use a much lower (3%) oil content. The oil (and polyethylene glycol monostearate) of Kimura, et al. are included merely as a dissolution adjuvant for indomethacin. Separation of the oil layer and aqueous layer will not occur at 3% oil content. This may be seen in Table 1 of the attached 132 Declaration. All 7 formulations have an oil component of 3%. In all cases, there is phase separation stability at least for the duration of the experiment (2 months at 5°C).

On the other hand, at an oil content of 7% (Table 2), of the 8 formulations, only two are stable for the duration of the experiment (2 months at 5°C). These two formulations contain either glyceryl monostearate or polyethylene glycol monostearate (40EO). As can be seen from Table 3, these two components both have "a melting point of 40°C or higher" as claimed. Accordingly, indomethacin-containing formulations according to the claimed invention have the advantage that there is no phase separation during storage, even though the oil content is high.

As discussed above, the advantage of a high oil content is a smooth feel when applied to skin. As shown in Table 4, the formulation prepared according to Kimura, et al. had a sticky feeling and irregularities in composition that is less appealing than the formulation prepared according to Example 1 of the present application. As explained in the present specification at (page 1, line 24-page 2, line 1), gel formulations have the disadvantage that, when in use, they exhibit irregularities which include a phenomenon in which a polymer collects like grime when the polymer is coated by rubbing.

Accordingly, Kimura, et al. do not teach all of the elements of the claimed invention such as use of a percentage of oil component in the range of 7-30% and "0.01 to 10 wt% of one or more components selected from the group consisting of glyceryl monostearate, sorbitan monostearate, stearyl alcohol, and polyethylene glycol monostearate...[with] a melting point of 40°C or higher". Furthermore, the combination of components in the stated concentration ranges as claimed provides a formulation with different and more attractive properties than taught by Kimura, et al. with respect to feel and appearance.

In view of Applicants' amendments, arguments, and the attached 132 Declaration, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present

disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Jan. 16, 2008

By: Che S. Chereskin

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ATTACHMENT A

Attachment A
page 1

TECHNICAL INFORMATION
PEG 400 MONO STEARATE
PRODUCT CODE : PEG 400 MS

SPECIFICATIONS :

ACID VALUE	1.00 MAX.
IODINE VALUE	1.00 MAX.
MELTING POINT	35 - 40 C
SPECIFIC GRAVITY	AT 30 0 C 1.0089
COLOUR GARDNER	3.0 MAX.

PROPERTIES / APPLICATIONS :-
PEG 400 MS is a quality ester formed by the reaction of high purity stearic acid and PEG 400 under specialised reaction conditions.PEG 400 MS is an emulsifier for oil - in - water emulsions and an auxiliary emulsifier for water - in - oil emulsions. In shampoos it is a hair conditioner and foam builder & known to improve cleansing action by preventing the redeposition of grease and dirt on the hair by a protective colloid effect. The main uses of PEG 400 MS are :-

1) In the manufacture of textiles , as lubricants in spinning and weaving .
2) In sizing , to provide easy desizing .
3) In scouring baths , as detergents and dispersants for lime and magnesium soaps.
4) In dyeing , to promote dispersion , penetration and leveling of dyes .
5) As emulsifier , in the manufacture of insecticidal and herbicidal sprays.
6) In the petroleum industry , for de - emulsifying crude oil emulsions.
7) In the pharmacutical and cosmetic industry , in the formulations of ointments , creams , lotions and suspensions .
8) as dispersants in the preparations of house hold cleaners.
9) In leather industry for softening of leather.

PACKING :-
20 KG NET IN POLYJARS OR 180 KG NET IN DRUMS.

STORAGE :-
UNDER DRY CONDITIONS AND AT ROOM TEMPERATURE .

Cat . ref. :- ES / 007 / 97

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tests which are believed to be reliable , is given without warranty. No liability can be accepted . Freedom from patent rights is not warranted.

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Technical Bulletin

MAPEG® 600 MS PEG (600) MONOSTEARATE

A Polyethylene Glycol Ester is a mono or diester of a fatty acid or oil reacted with a polyethylene glycol, with an average molecular weight usually designated within the product name.

Applications:
Polyethylene Glycol Esters can be used in liquid hand soaps, lotions, creams and shampoos, as emulsifiers, pearlizers, stabilizers, solubilizers and viscosity control agents. They also find use in the metalworking, pulp and paper, textile, household and institutional industries.

Solubilities:
Polyethylene Glycol Esters are available in graduated hydrophilic to lipophilic surface active properties. The lower molecular weight esters are oil soluble, and in non-aqueous systems, influence stability, viscosity, wetting, absorption, foaming and other physical properties. The mono and diesters of polyethylene glycol 200 and 300, and the diester of 400, are the most important for these properties. In aqueous systems Polyethylene Glycol Esters, with a molecular weight of 200 to 1450 are the most versatile in regard to emulsification, while the higher molecular weight distearate esters become excellent thickening agents.

Shelf Life:
BASF will endorse the results on the certificate of analysis for a period of up to one year from the date of manufacture for material in original, unopened, properly stored containers. Beyond one year, we recommend the quality of the material be confirmed prior to use, by retesting the certificate of analysis parameters.

MAPEG is a registered trademark of BASF Corporation

Specifications	
Acid Value, mg KOH/g	2 Max.
Saponification Value, mg KOH/g	62 – 70
Color, Gardner	2 Max.
Water, %	1 Max.

Typical physical properties	
Appearance @ 25 °C	White Waxy Solid
Melting Point, °C	41
HLB Value	13.6
Flashpoint, PMCC, °F	>350
Boiling Point, °F	>300
Solubility in Water @ 25 °C	Soluble

Please refer to the Material Safety Data Sheet (MSDS) for this product for instructions on safe and proper handling and disposal.

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